

II. REMARKS

After entry of the amendments presented herein, claims 2 to 38 will be pending in the subject application. New claims 2 to 38, which are directed towards alternative embodiments of the present invention, are presented herein for prosecution. Support for the new claims can be found throughout the specification, and as particularly identified in the Table of Exemplary Support for New Claims that follows:

Table of Exemplary Support for New Claims

2.	A dry reagent lateral flow strip assay device	The Field of the Invention describes a “dry reagent assay device” (1:21-22) that utilizes “lateral flow” (1:23).
	for detecting two or more analytes in a test sample comprising:	The assays described in the specification provide for the simultaneous assay of multiple analytes (1:22).
	a) a sample application zone; and	The “sample application zone” is specifically recited at 21:17-18. The specification refers to this part of the device as being, alternatively, a “sample pad, wicking material, transport matrix, or the like” (8:28)
	b) two or more test zones;	The specification describes that the assay may include “two or more test zones”(1:21)
	wherein the sample application zone and the two or more test zones are in fluid communication with one another through a transport matrix; and	This type of assay design is described at 1:22-24.
	wherein the transport matrix further comprises a lateral path along which the sample travels laterally, and a transverse path along which the sample travels transversely.	This assay design is described at 6:2-3, which recites that “[t]he sample flows in two dimensions laterally across a transport matrix and, subsequently, transverse to the transport

		matrix in a third dimension.” This configuration is also depicted in Figure 3 in which an assay can be performed to detect the presence of two or more analytes. This assay design is further described at 11:19-27.
3.	The assay device of claim 2 for performing general chemistry assays, wherein the two or more test zones are general chemistry reagent zones comprising at least one enzyme.	One type of assay that may be performed is a “general chemistry assay” (6:10) performed at one or more locations on the device. Impregnation with enzymes is described at 13:6. The general chemistry reagent zones are described at 13:8-13.
4.	The assay device of claim 2, wherein the two or more analytes are general chemistry analytes selected from the group consisting of: creatine, creatinine, glucose, cholesterol, high density lipoprotein (HDL) cholesterol, N-telopeptide, low density lipoprotein (LDL) cholesterol, triglycerides and blood urea nitrogen (BUN).	These exemplary analytes are described in the specification at 6:25-27, and also at 14:12-13.
5.	The assay device of claim 2, wherein the general chemistry reagent zone further comprises an indicator.	The inclusion of an indicator in the general chemistry reagent zone is described at 9:14-16.
6.	The assay device of claim 2 for performing a binding assay, wherein the two or more test zones are binding member zones comprising at least one binding member.	The specification describes that the assay device can be used to perform binding assays in general (6:26 to 7:28) using a “binding member” (6:29). The inclusion of binding member zones is described throughout the specification, and in particular at 19:11-26). For example, Zone 56 in Figure 15 is described as containing a member of a “binding pair”, i.e. it is a binding member zone (25:9-11).
7.	The assay device of claim 6, wherein the binding	The specification discloses

	member is an antibody.	the performance of immunoassays in the binding member zones, wherein the binding members are antibodies (6:27 to 7:1.
8.	The assay device of claim 2, wherein the two or more analytes are selected from the group consisting of: antigens, antibodies, macromolecules, vitamins, lectins, carbohydrates, proteins, peptides, amino acids, hormones, steroids, therapeutic drugs, drugs of abuse, bacterium and viruses.	These potential exemplary analytes are described at 7:1-28.
9.	The assay device of claim 2, wherein the two or more analytes are haptens that form binding pairs with antibodies.	This form of assay is described at 7:1.
10.	The assay device of claim 7, wherein the antibody is immobilized in the binding member zone.	Example 4 describes an assay having an antibody immobilized in the binding member zone (19:11-18).
11.	The assay device of claim 10, wherein the antibody is diffusively immobilized in the binding member zone.	Diffusive immobilization is described at 19:13.
12.	The assay device of claim 10, wherein the antibody is non-diffusively immobilized in the binding member zone.	Non-diffusive immobilization is described at 19:16.
13.	The assay device of claim 2, wherein the sample application zone further comprises a sample pad in fluid communication with the transport matrix.	Figure 1 describes "a pad which is in fluid communication" with the assay strip to which the transport matrix is associated (9:28), and which functions to receive the sample.
14.	The assay device of claim 13, further comprising a sample treatment pad in fluid communication with the transport matrix.	The sample treatment pad is recited at 12:24.
15.	The assay device of claim 14, wherein the sample treatment pad comprises a quaternary ammonium derived membrane for trapping ascorbate and other anionic interferents.	This assay design is described at 12:19-20.
16.	The assay device of claim 13, further comprising a sample filter pad in fluid communication with the transport matrix for removing undesired contaminants from the sample.	The use of a "sample filter pad which removes undesired contaminants from the sample", including "large particulate debris" is described at 9:29 to 10:1-2.
17.	The assay device of claim 13, wherein the sample pad removes large particulate debris from the sample.	The removal of "large particulate debris" in the sample pad, as opposed to

		its removal in a separate sample filter pad is described at 10:29.
18.	The assay device of claim 13, wherein the sample pad adjusts the pH and ionic composition of the sample.	The normalization of pH and ionic composition in the sample pad is described at 10:29-30, as opposed to being performed in a separate sample treatment pad.
19.	The assay device of claim 2, wherein the transport matrix is a porous material along which the sample travels laterally.	The transport matrix is described as being composed of a "porous material" at 8:18 along which the sample flows laterally (11:1).
20.	The assay device of claim 2, further comprising a metering layer between the transport matrix and the two or more test zones through which the sample spreads uniformly across the transport matrix.	The use of a metering layer to evenly distribute the sample transversely along the length of the transport matrix is described at 6:6-9.
21.	The assay device of claim 3, wherein the enzyme produces a reaction product when at least one of the analytes is present in the sample.	The formation of a reaction product is described at 9:3-4.
22.	The assay device of claim 6, wherein at least one of the binding members forms a complex with at least one analyte.	The formation of binding pairs is described at 6:30.
23.	The assay device of claim 5, wherein the indicator forms a detectable signal when at least one analyte is present in the sample	This type of assay is described at 9:14-16.
24.	The assay device of claim 6, wherein at least one of the binding member zones further comprises an indicator that forms a detectable signal when at least one analyte is present in the sample.	This type of assay is described at 9:9-16.
25.	The assay device of claim 2, further comprising a detection zone corresponding to each test zone.	As described in the specification, the signal can be produced directly in either the binding member zone or the general chemistry reagent zone, or the signal can be generated in a separate detection zone. This format is described on page 9, lines 4-6.
26.	A dry reagent lateral flow strip assay device	The Field of the Invention describes a "dry reagent assay device" (1:21-22) that utilizes "lateral flow"

		(1:23).
	for detecting two or more analytes in a test sample comprising:	The assays described in the specification provide for the simultaneous assay of multiple analytes (1:22).
	a) a sample application zone;	The “sample application zone” is specifically recited at 21:17-18. The specification refers to this part of the device as being, alternatively, a “sample pad, wicking material, transport matrix, or the like” (8:28)
	b) a general chemistry reagent zone comprising at least one enzyme; and	One type of assay that may be performed is a “general chemistry assay” (6:10) performed at one location on the device. Impregnation with enzymes is described at 13:6. The general chemistry reagent zones are described at 13:8-13.
	c) a binding member zone comprising at least one binding member;	The specification describes that the assay device can be used to perform binding assays in general (6:26 to 7:28) using a “binding member” (6:29). The inclusion of binding member zones is described throughout the specification, and in particular at 19:11-26). For example, Zone 56 in Figure 15 is described as containing a member of a “binding pair”, i.e. it is a binding member zone (25:9-11).
	wherein the sample application zone, the general chemistry reagent zone and the binding member zone are in fluid communication with one another through a transport matrix.	This type of assay design is described at 1:22-24.
27.	A diagnostic device for performing a dry reagent lateral flow assay on a strip comprising:	The diagnostic device of the present invention is described throughout the specification, and in particular at 5:25-28.

	a) a housing;	The housing is described at 9:23 and is depicted in Figure 1.
	b) a cover for the housing having an interior surface and an exterior surface, wherein a sample receptor extends therethrough;	The cover is described at 9:23-25 and is depicted in Figure 1.
	c) a sample pad;	The sample pad is described at 9:26-29 and is depicted in Figure 1.
	d) at least one assay strip in fluid communication with the sample pad, wherein the assay strip comprises at least two test zones; and	The assay strip is described at 9:28 and is depicted in Figure 1.
	e) a reflectometer enclosed in the housing adapted to transmit results from the assay.	"The interior 110 of the housing encloses a reflectometer" (10:5)
28.	The device of claim 27, wherein the sample receiving device further comprises a sample filter pad.	"Optionally, the sample receiving device 114 can also include a sample filter pad which removes undesired contaminants from the sample" (9:29-30).
29.	The device of claim 27, wherein the sample receiving device removes undesired contaminants from the sample.	This describes the configuration "with one pad performing both (sp) functions" (10:1), i.e. to receive sample and remove contaminants.
30.	The device of claim 27, wherein the assay strip further comprises at least one sample filter pad.	The inclusion of the "sample filter pad along the pathway of the sample flow which remove[s] different types of contaminants" (10:2-3).
31.	The device of claim 27, wherein the reflectometer further comprises a printed writing assembly having a printed circuit board.	In one embodiment, the reflectometer "includes a printed wiring assembly having a printed circuit board" (10:5-6) which is depicted in Figure 1
32.	The device of claim 27, wherein the reflectometer further comprises an optics assembly.	In one embodiment, "the reflectometer (126) also includes an optics assembly" (10:7) and is depicted in Figure 1.
33.	The device of claim 31, wherein the printed circuit board has a face with at least two zone detectors mounted directly thereto.	This configuration is described at 10:7-8 and is depicted in Figure 1.
34.	The device of claim 32, wherein the optics assembly	This aspect of the device is

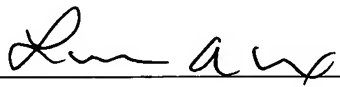
	is configured to translate reflected signal from the test zones into a reflectance reading.	described at 10:21-26, and also at 13:27-29.
35.	A method for detecting two or more analytes in a test sample using a dry reagent lateral flow strip assay device, comprising the steps of:	See claim 2.
	a) preparing an assay device comprising a sample application zone and two or more test zones in fluid communication with one another through a transport matrix, wherein the transport matrix further comprises a lateral path along which the sample travels laterally, and a transverse path along which the sample travels transversely;	See claim 2.
	b) applying a sample to the sample application zone;	The application of the sample to the sample pad is described at 10:28-29.
	c) permitting the sample to flow along the lateral path and the transverse path; and	The flow of the sample is described at 10:30 to 11:2.
	d) detecting a signal from the test zones.	The detection of signal, and in particular color, is described at 10:9-13.
36.	The method of claim 35, wherein the test sample is derived from whole blood, whole blood components, ascites, urine, sweat, milk, synovial fluid, peritoneal fluid, amniotic fluid or cerebrospinal fluid.	These exemplary samples are described at 8:1-3.
37.	The method of claim 35, wherein the sample is pretreated prior to application.	Pretreatment is described at 8:4.
38.	A system for detecting two or more analytes in a test sample comprising:	See claim 2.
	a) a dry reagent lateral flow strip assay device, wherein the strip assay device comprises: i) a sample application zone; and ii) two or more test zones; wherein the sample application zone and the two or more test zones are in fluid communication with one another through a transport matrix; and	See claim 2.
	b) the diagnostic device of claim 27.	See claim 27.

III. CONCLUSION

Applicants contend that all pending claims in this case are in condition for allowance. The examiner is cordially invited to telephone the undersigned at 619-446-5622 should she/he believe that a discussion could resolve any outstanding issues.

Respectfully submitted,
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